EXHIBIT 14

DEPARTMENT OF HEALTH& HUMAN SERVICES

Office of Inspector General

Memorandum

Date · JUL 11 1996

From June Gibbs Brown
Inspector General

Subject Review of Pharmacy Acquisition Costs for Drugs Reimbursed Under the Medicaid Prescription Drug Program of the Montana Department of Public Health and Human Services (A-06-95 -OO068)

To Bruce C. Vladeck
Administrator
Health Care Financing Administration

Attached for your information and use is our final report entitled, "Review of Pharmacy Acquisition Costs for Drugs Reimbursed Under the Medicaid Prescription Drug Program of the Montana Department of Public Health and Human Services." This review was conducted as part of a nationwide audit of pharmacy drug acquisition costs at the Health Care Financing Administration's request. Most States reimburse pharmacies for Medicaid prescriptions using a formula which generally discounts the average wholesale price (AWP) by 10.5 percent. The objective of our review was focused on developing an estimate of the difference between the actual acquisition costs of drugs of pharmacies and AWP for both brand name and generic drugs.

The Montana Department of Public Health and Human Services (State Agency) was 1 of 11 States randomly selected as part of the nationwide review. Montana reported drug expenditures of $26 million in Calendar Year 1994.

Through statistical sampling, we obtained pricing information from 43 Montana pharmacies. We obtained 2,924 invoice prices for brand name drugs, and 1,662 invoice prices for generic drugs. The overall estimate of the extent that AWP exceeded pharmacy purchase invoice prices was 16.2 percent for brand name drugs and 48.5 percent for generic drugs. The national estimates are 18.3 percent and 42.5 percent, respectively. The estimates combine the results for four categories of pharmacies including rural-chain, rural-independent, urban-chain, and urban-independent. The estimates exclude the results obtained from non-traditional pharmacies (nursing home pharmacies, hospital pharmacies, home IV, etc.) because such pharmacies purchase drugs at substantially greater discounts than retail pharmacies, and including them would have inappropriately inflated our percentages.

We are recommending that the State Agency consider the results of this review as a factor in any future changes to pharmacy reimbursement for Medicaid drugs.

In response to our draft report, the State Agency expressed concerns about the evaluation of Medicaid pharmacy pricing. The State Agency also raised questions concerning the further discounting of AWP in pricing formulas and the effect of its result. The State Agency's comments are incorporated in our final report.

We welcome any comments you have on this Montana State report. If you have any questions, please call me or have your staff contact George M. Reeb, Assistant Inspector General for Health Care Financing Audits, at (410) 786-7104.

To facilitate identification, please refer to Common Identification Number A-06 -95-OO068.

Attachment

Department of Health and Human Services

OFFICE OF INSPECTOR GENERAL

REVIEW OF PHARMACY ACQUISITION COSTS FOR DRUGS REIMBURSED UNDER THE MEDICAID PRESCRIPTION DRUG PROGRAM OF THE MONTANA DEPARTMENT OF PUBLIC HEALTH AND HUMAN SERVICES

JUNE GIBBS BROWN
Inspector General

JULY 1996
A-06-95-00068

SUMMARY

At the request of the Health Care Financing Administration (HCFA), the Office of Inspector General (OIG) conducted a nationwide review of pharmacy acquisition costs for drugs reimbursed under the Medicaid prescription drug program. Since most States reimburse pharmacies for Medicaid prescriptions using a formula which discounts the average wholesale price (AWP), the objective of our review was to develop an estimate of the difference between the actual acquisition costs of drugs of the pharmacies and AWP for both brand name and generic drugs.

To accomplish our objective, we selected a random sample of 11 States from a universe of 48 States and the District of Columbia. Arizona was excluded from the universe of States because the Medicaid drug program is a demonstration project using prepaid cavitation financing and Tennessee was excluded because of a waiver received to implement a statewide managed care program for Medicaid. Montana was one of the sample States, as well as California, Delaware, District of Columbia, Florida, Maryland, Missouri, Nebraska, New Jersey, North Carolina, and Virginia.

Additionally, we selected a sample of Medicaid pharmacy providers from each State and obtained invoices of their drug purchases. The pharmacies were selected from each of five categories--rural-chain, rural-independent, urban-chain, urban-independent, and non-traditional pharmacies (nursing home pharmacies, hospital pharmacies, etc.). We included the non-traditional category so as to be able to exclude those pharmacies from our overall estimates. We believed such pharmacies purchase drugs at substantially greater discounts than retail pharmacies, and including them would have inflated our percentages.

We compared each invoice drug price to AWP for that drug and calculated the percentage, if any, by which AWP exceeded the invoice price. We then projected those differences to the universe of pharmacies in each category for each State and calculated an overall estimate for each State. Additionally, we projected the results from each State to estimate the nationwide difference between AWP and invoice price for each category.

In Montana, we obtained pricing information from 43 pharmacies. Specifically, we obtained 2,924 invoice prices for brand name drugs, and 1,662 invoice prices for generic drugs. For Montana, the overall estimate of the extent that AWP exceeded invoice prices was 16.2 percent for brand name drugs and 48.5 percent for generic drugs. The national estimates are 18.3 percent and 42.5 percent, respectively. The estimates combine the results for four categories of pharmacies including rural-chain, rural-independent, urban-chain, and urban-independent and exclude the results obtained from non-traditional pharmacies.

We are recommending that the Montana Department of Public Health and Human Services (State Agency) consider the results of this review as a factor in any future changes to pharmacy reimbursement for Medicaid drugs. We will share the information with HCFA from all 11 States in a consolidation report for their use in evaluating the overall Medicaid drug program.

The Director of the State Agency responded to our draft report in a letter dated April 4, 1996. The State Agency stated that any evaluation of Medicaid pharmacy pricing should also consider the dispensing fee portion of the payment formula and the effect of Federal upper limit pricing for generic drugs. The State Agency was also concerned that further discounting of AWP in pricing formulas would result in a corresponding inflation of AWP.

We agree with the Director that acquisition cost is just one factor to consider in evaluating Medicaid pharmacy reimbursement. We also agree that inflation of AWP could result from further discounting AWP in pricing formulas. However, we believe that information on prices actually paid by pharmacies will be useful to both HCFA and the States in setting future pharmacy reimbursement for the ingredient cost of drugs. The full text of the Director's comments is included in Appendix 4.

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INTRODUCTION

At the request of HCFA, OIG, Office of Audit Services (OAS) conducted a review of pharmacy acquisition costs for drugs reimbursed under the Medicaid prescription drug program of the Montana Department of Public Health and Human Services (State Agency). The objective of our review was to develop an estimate of the difference between the actual acquisition costs of drugs and AWP. This review was conducted as apart of a nationwide review of pharmacy acquisition costs. Montana was 1 of 11 States randomly selected as part of the nationwide review.

BACKGROUND

Medicaid regulations provide for the reimbursement of drugs using two methods. If a drug is a multiple source (generic) drug, then reimbursement is based on the lower of the pharmacist's usual and customary charge to the general public or an upper limit amount plus a dispensing fee. The Federal upper limit amounts are established by HCFA. If a drug is a single source (brand name) drug, or a generic drug for which an upper limit amount has not been established, then the reimbursement is the lower of the pharmacist's usual and customary charge to the general public or the estimated acquisition cost (EAC) plus a reasonable dispensing fee. The State agencies are responsible for determining the EAC and the dispensing fee.

The EAC for most States is calculated by using AWP for a drug less some percentage. The AWP is the price assigned to the drug by its manufacturer and is listed in either the ***Red Book, Medispan*** or the ***Blue*** Book--publications universally used in the pharmaceutical industry. Prior to 1984, most States used 100 percent of AWP for reimbursement of acquisition costs. However, OIG issued a report in 1984 which stated that, on average, pharmacies purchased drugs for 15.9 percent below AWP. In 1989, OIG issued a follow-up report which concluded that pharmacies were purchasing drugs at discounts of 15.5 percent below AWP. Both the 1984 and 1989 reports combined brand name and generic drugs in calculating the percentage discounts and included a comparison of 3,469 and 4,723 purchases, respectively.

In 1989, HCFA issued a revision to the State Medicaid Manual which pointed out that a preponderance of evidence demonstrated that AWP overstated prices that pharmacies actually paid for drugs by as much as 10 to 20 percent. The Manual further provided that, absent valid documentation to the contrary, it would not be acceptable for a State to make reimbursements using AWP without a significant discount.

In November 1990, the Omnibus Budget Reconciliation Act of 1990 was passed which placed a 4-year moratorium on changes to States' reimbursement policies. The moratorium expired on December 31, 1994 and HCFA requested that we, once again, determine the difference between AWP and actual pharmacy acquisition cost.

The State Agency reported drug expenditures of $26 million in Calendar Year (CY) 1994.

SCOPE

Our review was performed in accordance with generally accepted government auditing standards. The objective of our review was to develop an estimate of the difference between AWP and the actual invoice prices of both brand name and generic prescription drugs to Medicaid pharmacy providers. Our objective did not require that we identify or review any internal control systems.

Our review was limited to ingredient acquisition costs and did not address other areas such as: the effect of Medicaid business as a contribution to other store sales; the cost to provide professional services other than dispensing a prescription such as therapeutic interventions, patient education, and physician consultation; and the cost of dispensing which includes costs for computers, multi-part labels, containers, technical staff, transaction fees, Medicaid specific administrative costs, and general overhead. We also did not take into consideration the effect of Federal upper limit amounts on generic drug reimbursements or usual and customary charge limitations. We plan to evaluate the effect of the Federal upper limit amounts on generic drug reimbursements in a subsequent review.

We obtained a listing of all Medicaid pharmacy providers from the State Agency. The State Agency was responsible for classifying each pharmacy as chain, independent or non-traditional. For purposes of this review, a chain was defined as four or more pharmacies with common ownership. We determined whether each pharmacy was rural or urban by comparing the county location for each pharmacy to a December 31, 1992 listing of metropolitan areas and their components. We selected a stratified random sample of 60 pharmacies with 12 pharmacies selected from each of 5 strata--rural-chain, rural-independent, urban-chain, urban-independent, and non-traditional (nursing home pharmacies, hospital pharmacies, home IV, etc.). We included the non-traditional category so as to be able to exclude those pharmacies from our estimates. We believed that such pharmacies are able to purchase drugs at substantially greater discounts than a retail pharmacy and would inflate our estimate.

We requested, from each pharmacy selected, the largest invoice from each different source of supply for a specified month in CY 1994. We identified the sources of supply as wholesalers, chain warehouse distribution centers, generic distributors, and direct manufacturer purchases. Each pharmacy was assigned a month from January through September in order to provide a cross-section of this 9-month time period. However, we permitted one pharmacy to provide invoices from December as invoices were not available from the earlier period.

We reviewed every line item on the invoices supplied by the sample pharmacies to ensure that the invoices contained the information necessary for our review. We eliminated over-the-counter items. Some invoices did not include National Drug Codes (NDC), which were needed to obtain

AWP for the drug. We attempted to obtain NDCS in those instances. We used the 1994 ***Red Book,*** a nationally recognized reference for drug product and pricing information, as a reference for drug product and pricing information, as a reference to obtain NDCS or identify over-the-counter items. One prominent wholesaler, whose invoices contained that wholesaler's item number rather than NDCs, provided us with a listing that converted their item number to an NDC. If we were unable to identify the NDC for a drug, we eliminated the drug. This was a common occurrence for generic drugs where there was no indication on the invoice as to the manufacturer of the drug.

We obtained a listing from HCFA that indicated whether a drug is a brand name or generic drug. We used that listing to classify each drug on the invoices as brand or generic. If a drug was not on the HCFA listing, we used the ***Red Book*** to determine whether the drug was brand or generic. Additionally, we obtained drug expenditure information from HCFA-64 Reports.

The State of Montana provided us with a pricing file for the purpose of obtaining the AWP for each drug. We compared the invoice drug price to AWP for each drug and calculated the percentage, if any, by which AWP exceeded the invoice price. If a drug from an invoice was not on the pricing file we eliminated that drug.

An initial meeting was held in Richmond, Virginia on August 30-31, 1994, with Medicaid pharmacy representatives from the sample States. At this meeting, we presented a methodology for performing the review and the methodology was refined with input from the State representatives. At a follow-up meeting held in Richmond, Virginia, on September 27-28, 1995, we presented the results of our review with the sample States.

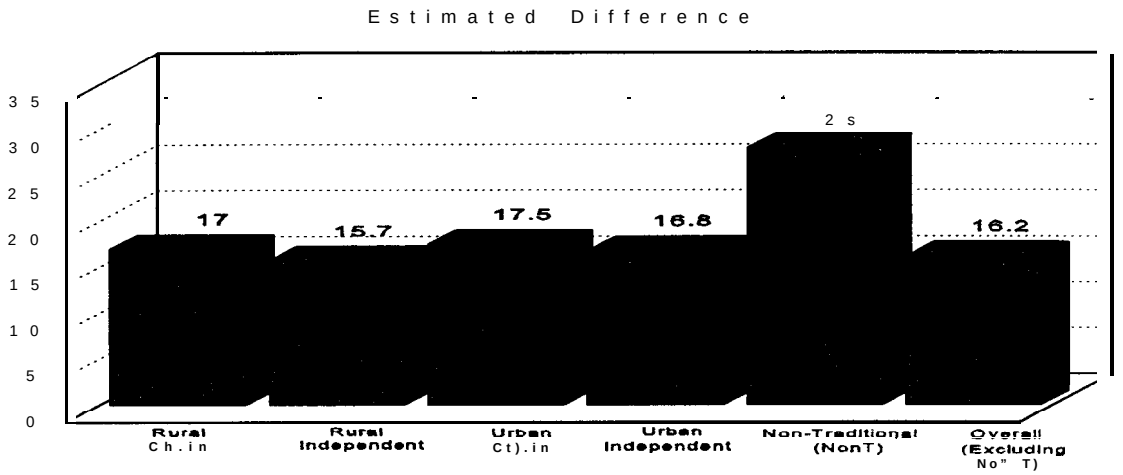
We used OAS statistical computer software to calculate all estimates as well as to generate all random numbers. We did not independently verify any information obtained from third party sources. Our review was conducted by our Little Rock, Arkansas OAS field office with assistance from our OAS field offices in Baton Rouge, Louisiana, and Austin, Texas from "September 1994 to September 1995.

FINDINGS AND RECOMMENDATIONS

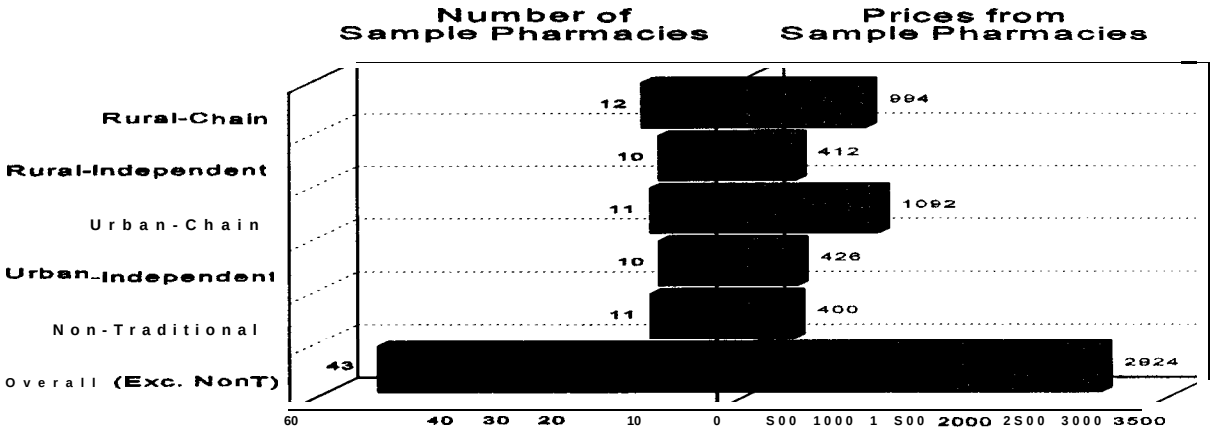
BRAND NAME DRUGS

We estimate that AWP exceeded invoice prices for *brand name drugs* by 16.2 percent. The estimate combined all pharmacy categories except for non-traditional pharmacies and was based on the comparison to AWP of 2,924 invoice prices received from ***43*** pharmacies. The standard deviation for this estimate was 0.56 percent (see Appendix 2).

The estimates that AWP exceeded invoice prices for *brand name drugs* are summarized in the following table:



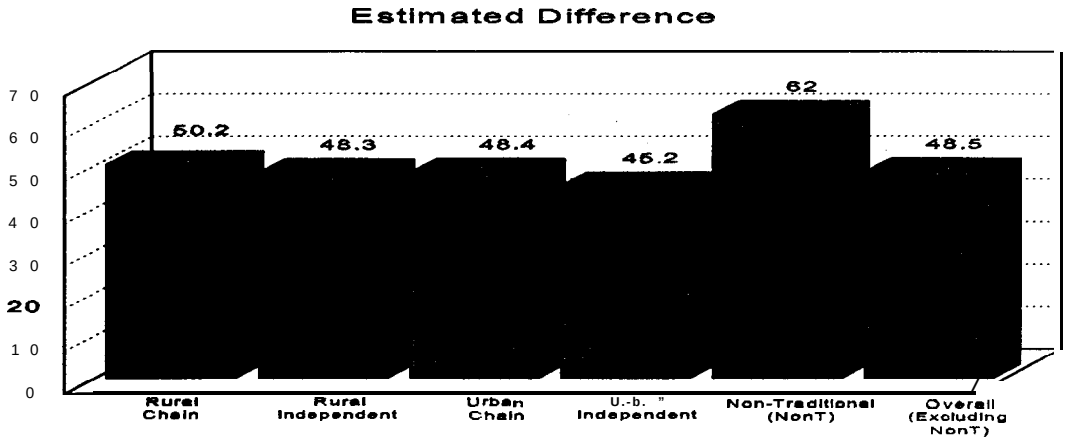
The following table shows the number of pharmacies sampled and the number of prices reviewed by individual category for *brand name drugs*.



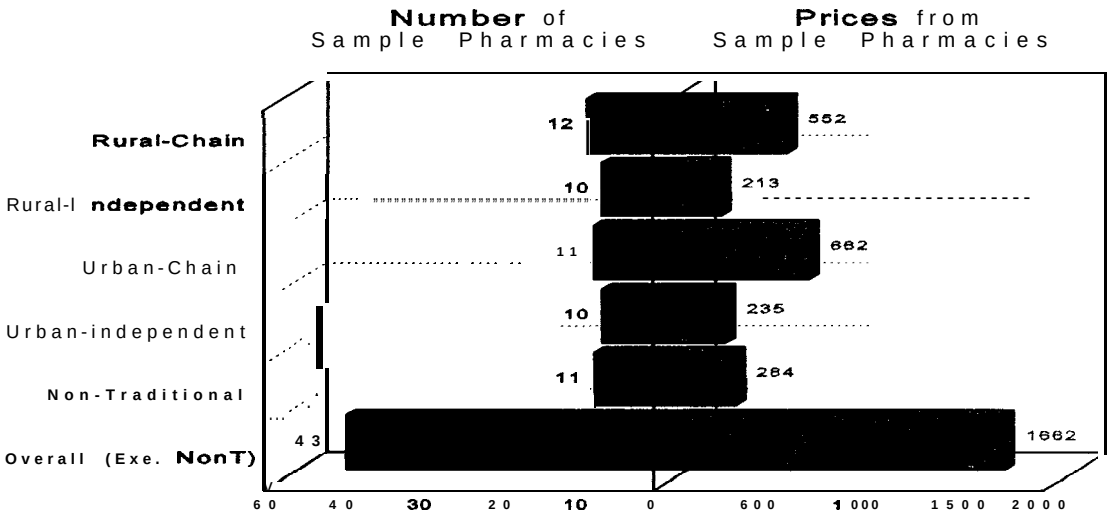
GENERIC DRUGS

We estimate that AWP exceeded invoice prices for *generic drugs* by 48.5 percent. Once again, the estimate combined all pharmacy categories except non-traditional pharmacies. The estimate was based on the comparison to AWP of 1,662 invoice prices received from 43 pharmacies. The standard deviation for this estimate was 1.51 percent (see Appendix 2).

The estimates that AWP exceeded invoice prices for *generic drugs* are summarized by individual categories in the following table:



The following table shows the number of pharmacies sampled and the number of prices reviewed by individual category for the *generic drugs.*



CONCLUSIONS AND RECOMMENDATION

Based on our review, we have determined that there is a significant difference between AWP and pharmacy acquisition costs. The difference between AWP and pharmacy acquisition costs is significantly greater for generic drugs than for brand name drugs. In general, State representatives believed that the review supported current State practices to establish pharmacy reimbursement for ingredient cost at levels below AWP.

We recognize that acquisition cost is just one factor in pharmacy reimbursement policy and that any change to that policy should also consider the other factors discussed in the Scope section of our report. Additionally, the effect of Federal upper limit amounts on generic drug reimbursements or usual and customary charge limitations should be taken into consideration. However, a change in any of the factors affecting pharmacy reimbursement could have a significant impact on expenditures because of the size of the program ($26 million) in Montana. We believe that the difference between AWP and pharmacy acquisition costs as determined by our review is significant enough to warrant consideration by the State in any evaluation of the drug program. Therefore, we recommend that the State Agency consider the results of this review in determining any future changes to pharmacy reimbursement for Medicaid drugs.

STATE AGENCY'S COMMENTS

The Director of the State Agency responded to our draft report in a letter dated April 4, 1996. The Director stated that any evaluation of Medicaid pharmacy pricing should also consider the dispensing fee portion of the payment formula and the effect of Federal upper limit pricing for generic drugs. The Director was also concerned that further discounting of AWP in pricing formulas would result in a corresponding inflation of AWP.

OIG'S RESPONSE

We agree with the Director that acquisition cost is just one factor to consider in evaluating Medicaid pharmacy reimbursement. We also agree that inflation of AWP could result from further discounting AWP in pricing formulas. However, we believe that information on prices actually paid by pharmacies will be useful to both HCFA and the States in setting future pharmacy reimbursement for the ingredient cost of drugs. The full text of the Director's comments is included in Appendix 4.

APPENDICES

SAMPLE DESCRIPTION

Sample Objectives:

Develop an estimate of the extent that Average Wholesale Prices (AWP) exceed actual invoice prices to Medicaid pharmacies in Montam for brand name drugs and for generic drugs.

Population:

The sampling population was pharmacy providers participating in the Medicaid prescription drug program of the State Agency.

Sampling Frame:

The sampling frame was a listing of all pharmacy providers participating in the Medicaid prescription drug program.

Sample Design:

A sample of 12 pharmacies was randomly selected from each of 5 strata. The five strata of pharmacies were rural-chain, rural-independent, urban-chain, urban-independent, and non-traditional (nursing home pharmacies, hospital pharmacies, home IV, etc.). Each pharmacy was assigned a month from 1994 for which to provide invoices. All pharmacies were initially assigned a month from January through September in a method designed to provide a cross-section of the 9-month period. However, some pharmacies were permitted to submit invoices from November or December as invoices were not available for the month originally assigned. The largest invoice from each of four different sources of supply was requested. The sources of supply were identified as wholesalers, chain warehouse distribution centers, generic distributors, and direct manufacturer purchases. All invoice prices were compared to AWP.

Sample Size:

Twelve pharmacies were selected from each stratum for a total of 60 pharmacies.

Source of Random Numbers:

OAS statistical sampling software was used to generate the random numbers.

Characteristics to be Measured:

From our review of the pharmacy invoices, we calculated the percentage that AWP exceeded actual invoice prices for all drugs on the invoices submitted.

Treatment of Missing Sample Items:

No spare was substituted for a pharmacy that did not provide information. If a pharmacy did not send an invoice for a particular type of supplier, we assumed that the pharmacy did not purchase drugs from that type of supplier during the month assigned to the pharmacy.

Estimation Methodology:

We used OAS Statistical Software to project the percentage difference between AWP and actual invoice prices for each stratum, as well as an overall percentage difference. The overall percentage difference excluded the non-traditional pharmacies. The projections were done separately for brand name drugs and generics.

Other Evidence:

We obtained AWP from First DataBank.

APPENDIX 2

MONTANA SAMPLE RESULTS
BRAND NAME AND GENERIC DRUGS

	CATEGORY	SAMPLE UNIVERSE	SAMPLE SIZE	DRUG PRICES REVIEWED	POINT ESTIMATE	STANDARD DEVIATION	90 PERCENT CONFIDENCE LEVEL LOWER LIMIT	90 PERCENT CONFIDENCE LEVEL UPPER LIMIT
BRAND	RURAL-CHAIN	43	12	994	17.0	1.89	16.19	17.71
BRAND	RURAIANDEPENDENT	118	10	412	15.77	3.09	14.11	17.19
BRAND	URBAN-CHAIN	23	11	1,092	17.15	2.22	16.61	18.24
BRAND	URBAN-INDEPENDENT	16	10	426	16.88	1.37	16.31	17.23
BRAND	NON-TRADITIONAL	45	11	400	28.0	8.41	24.40	31.65
BRAND	OVERALL (EXCL. NON-TRAD)	200	43	2,924	16.22	0.56	15.30	17.10
GENERIC	RURALCHAIN	43	12	552	50.21	9.38	46.43	53.99
GENERIC	RURALINDEPENDENT	118	10	213	48.31	7.89	44.35	52.21
GENERIC	URBAN-CHAIN	23	11	662	48.41	8.43	45.33	51,38
GENERIC	URBAN-INDEPENDENT	16	10	235	45.21	8.25	42.55	47.83
GENERIC	NON-TRADITIONAL	45	11	284	62.0	12.72	56.47	67.44
GENERIC	OVERALL (EXCL. NON-TRAD)	200	43	1.662	48.25	1.51	45.97	50.94

APPENDIX 3

NATIONWIDE SAMPLE RESULTS
BRAND NAME AND GENERIC DRUGS

	NATIONWIDE	SAMPLE UNIVERSE	SAMPLE SIZE	. . . DRUG PRICES REVIEWED	POINT I ESTIMATE	STANDARD E ERROR R	90 PERCENT CONFIDENCE LEVEL LOWER LIMIT	90 PERCENT CONFIDENCE LEVEL UPPER LIMIT
BRAND	RURAL-CHAIN	1,095	73	5,723	17.4	1.05	15.67	19.13
	RURAL-INDEPENDENT	1,495	78	3,043	16.4	1.07	14.63	18.15
	URBAN-CHAIN	8,194	73	7,198	18.5	0.52	17.60	19.31
	URBAN-INDEPENDENT	6,242	91	3,009	18.7	0.90	17.22	20.19
	NON-TRADITIONAL	2,026	66	1,762	27.5	2.28	23.76	31.27
	OVERALL (EXCL. NON-TRAD	17,030	315	18,973	18.3	0.66	17.21	19.38
GENERIC	RURAL-CHAIN	1,09!	73	2,963	47.5	1.63	44.82	50.20
	RUIL4L-INDEPENDENT	1,495	78	1,798	47.4	0.93	45.85	48,92
	URBAN-CHAIN	8,194	72	2,634	37.6	2.82	32.97	42.26
	URBAN-INDEPENDENT	6,242	91	1,680	46.7	2.44	42.70	50.73
	NON-TRADITIONAL	2,026	5s	1,262	57.7	1.98	54.43	60.96
	OVERALL (EXCL. NON-TRAD	17,03(	314	9.075	42.5	0.90	40.97	43.93

DEPARTMENT OF
PUBLIC HEALTH AND HUMAN SERVICES

MARC RACICOT
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PETER S. BLOUKE, PhD
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STATE OF MONTANA

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April 4, 1996

Mr. George M. Reeb, Asst. Inspector General
Department of Health and Human Services
Office of the Inspector General
330 Independence Avenue, S.W.
Washington, D.C. 20201

Dear Mr. Reeb:
On March 29, 1996, the Montana Department of Health and Human Services received the draft report of a review of pharmacy acquisition costs. The study results indicate the national average acquisition costs for brand products are estimated to be AWP minus 18.3 percent and for generic products they are estimated to be AWP minus 42.45% . Montana's corresponding average discounts as computed by the OIG are 16.23% and 48.46% respectively. Montana currently pays the lesser of AWP minus 10%, Federal upper limit for multi-source generic products. In addition to the product cost Medicaid also reimburses a dispensing fee not to exceed $4.08 per script and limits payment for the total of both components to the usual and customary charge for the prescription..

It is important to note that the study did not investigate the payment of these services by Medicaid, only the cost of acquisition of the drug by the providers. We believe all states involved are concerned that if these numbers are directly compared to the discounted AWP method of Medicaid Pharmacy pricing, confusion and questions will arise. The two major factors that must also be considered if this comparison is done relate to the dispensing fee portion of the payment formula and the effect of Federal upper limit (FUL) pricing for generic drugs. No work was performed by the OIG to determine how total reimbursement for pharmacy services relates to the cost of providing the service.

It is expected that when these results are published that the immediately concerns will be raised that pharmacy providers are being reimbursed more than the acquisition cost of the products and that changes should be made to the pricing formula to increase the discount on AWP. In order to address these concerns, states must do additional work to determine whether the cost to dispense is being accurately reimbursed and what effect the FUL pricing has on the discount for generic. In Montana we currently believe that the dispensing fee is below the cost to dispense because of the capon dispensing fees that is currently in place and has been for many years. Unfortunately, the FUL affect is not known at this time. The OIG has offered to release the base data so that FUL impact can be calculated by the states, but these data are not expected to be

received until after the findings are published. At that time , work could be performed to determine the impact of FUL on generic pricing.

We also believe that further discounting the AWP in pricing formulas will result in a corresponding inflation of AWP to mitigate the impact. This might result in a cycle of action and reaction that results in increased administrative burden but little savings to Medicaid. Caution and careful thought should precede action in addressing this situation.

It is imperative that this information be given equal consideration in any evaluation of Medicaid pharmacy pricing so that improper assumptions and conclusion are not made.

If you have any questions, please contact Terry Krantz of my staff at (406)444-4145. We appreciate the cooperation and inclusion in this process and look forward to continuing this excellent working relationship.

Sincerely,

Michael S Billings

Peter S. Blouke, Ph.D.
Director

cc: Mary Dalton
Nancy Ellery
Terry Krantz
Jeff Ireland